

DOCKET NO.: A0752.70001US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Stahl et al.
Serial No.: 09/464,303
Confirmation No.: 7348
Filed: December 15, 1999
For: METHODS AND PRODUCTS FOR REGULATING LECTIN
COMPLEMENT PATHWAY ASSOCIATED COMPLEMENT
ACTIVATION
Examiner: Francois P. Vandervegt
Art Unit: 1644

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 2 day of August, 2004.

Kristin J. Ketelhus
Kristin J. Ketelhus

MAIL STOP AMENDMENT

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- ☒ Information Disclosure Statement
- ☒ PTO Form 1449 with cited references
- ☒ Return Receipt Postcard

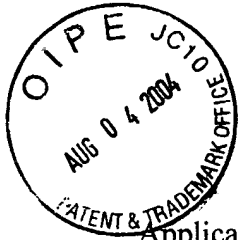
If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check in the amount of \$180 is enclosed to cover the filing fee. If the fee is insufficient, the balance may be charged to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,
Stahl et al., Applicant

By: *Janice A. Vatland*
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Docket No. A0752.70001US00
Date: August 2, 2004
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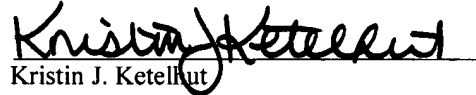
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Kristin J. Ketellut

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**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180 as set forth in 37 C.F.R. §1.17(p) is enclosed.

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PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
A0752.70001US01	10/766,755	28 January 2004	Stahl et al.

The Applicant would like to bring to the Examiner's attention the enclosed search report(s) or other communication(s) from corresponding International or Foreign National Application(s).

<u>Docket No.</u>	<u>Serial No.</u>	<u>Date of Mailing</u>	<u>Type of Communication</u>
A0752.70001WO00	PCT/US99/29919	22 February 2001	International Preliminary Examination Report
A0752.70001WO00	PCT/US99/29919	6 April 2000	International Search Report
A0752.70001EP00	EPO/99967362.7	24 January 2002	European Search Report
A0752.70003WO00	PCT/US00/22123	26 November 2001	International Preliminary Examination Report
A0752.70003WO00	PCT/US00/22123	27 September 2001	Written Opinion
A0752.70003WO00	PCT/US00/22123	21 September 2001	Written Opinion
A0752.70003WO00	PCT/US00/22123	30 March 2001	Written Opinion
A0752.70003WO00	PCT/US00/22123	29 December 2000	International Search Report

The Applicant would like to bring to the Examiner's attention the following other information:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Date of Mailing</u>	<u>Type of Document</u>
A0752.70003US00	09/638,420	21 October 2003	Office Communication
A0752.70003US00	09/638,420	14 January 2003	Office Communication

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

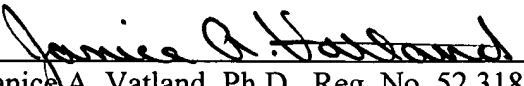
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,
Stahl et al., Applicant

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Janice A. Vatland, Ph.D., Reg. No. 52,318
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FORM PTO-1449/A and B (Modified)		APPLICATION NO.: 09/464,303	ATTY. DOCKET NO.: A0752.70001US00
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		FILING DATE: December 15, 1999	CONFIRMATION NO.: 7348
		APPLICANT: Stahl et al.	
		GROUP ART UNIT: 1644	EXAMINER: Francois P. Vandervegt
Sheet	1	of	



U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		

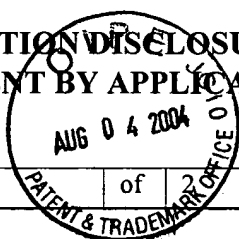
FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B10	WO	90/08549	A1	Speck, Ulrich	08-09-1990	Abstract only
	B11	WO	93/18775	A1	The University of British Columbia	09-30-1993	
	B12	WO	97/31121	A1	The University of British Columbia	08-28-1997	

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C39	AGAH et al., Isolation, cloning and functional characterization of porcine mannose-binding lectin. Immunology. 2001 Mar;102(3):338-43.	
	C40	BHOLE et al., Therapeutic potential of targeting the complement cascade in critical care medicine. Crit Care Med. 2003 Jan;31(1 Suppl):S97-104. Review.	
	C41	BLUME et al., Activated endothelial cells elicit paracrine induction of epithelial chloride secretion. 6-Keto-PGF1alpha is an epithelial secretagogue. J Clin Invest. 1998 Sep 15;102(6):1161-72.	
	C42	COLLARD et al., Complement activation following reoxygenation of hypoxic human endothelial cells: role of intracellular reactive oxygen species, NF-kappaB and new protein synthesis. Immunopharmacology. 1998 Mar;39(1):39-50.	
	C43	COLLARD et al., Complement activation following oxidative stress. Mol Immunol. 1999 Sep-Oct;36(13-14):941-8. Review.	
	C44	COLLARD et al., Endothelial oxidative stress activates the lectin complement pathway: role of cytokeratin 1. Am J Pathol. 2001 Sep;159(3):1045-54.	
	C45	COLLARD et al., Complement activation after oxidative stress: role of the lectin complement pathway. Am J Pathol. 2000 May;156(5):1549-56.	
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	C48	FIANE et al., Mechanism of complement activation and its role in the inflammatory response after thoracoabdominal aortic aneurysm repair. Circulation. 2003 Aug 19;108(7):849-56. Epub 2003 Aug 04.	
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	C50	HOLT et al., Domain antibodies: proteins for therapy. Trends Biotechnol. 2003 Nov;21(11):484-90. Review.	
	C51	IGARASHI et al., Specific binding of a synthetic peptide derived from an antibody complementarity determining region to phosphatidylserine. J Biochem (Tokyo). 1995 Feb;117(2):452-7.	
	C52	JORDAN et al., Inhibition of mannose-binding lectin reduces postischemic myocardial reperfusion injury. Circulation. 2001 Sep 18;104(12):1413-8.	
	C53	KINGMAN, Complement activation in myocardial infarction: A target for future treatments? Drug Discovery Today. 2000; 8: 313-4.	
	C54	LANZREIN et al., Mannan-binding lectin in human serum, cerebrospinal fluid and brain tissue and its role in Alzheimer's disease. Neuroreport. 1998 May 11;9(7):1491-5.	

FORM PTO-1449/A and B (Modified)		APPLICATION NO.: 09/464,303	ATTY. DOCKET NO.: A0752.70001US00
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		GROUP ART UNIT: 1644	EXAMINER: Francois P. Vandervegt
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C55	LAUNE et al., Systematic exploration of the antigen binding activity of synthetic peptides isolated from the variable regions of immunoglobulins. J Biol Chem. 1997 Dec 5;272(49):30937-44.
C56	LEKOWSKI et al., Ulex europaeus agglutinin II (UEA-II) is a novel, potent inhibitor of complement activation. Protein Sci. 2001 Feb;10(2):277-84.
C57	MONNET et al., Synthetic peptides derived from the variable regions of an anti-CD4 monoclonal antibody bind to CD4 and inhibit HIV-1 promoter activation in virus-infected cells. J Biol Chem. 1999 Feb 5;274(6):3789-96.
C58	MONTALTO et al., A keratin peptide inhibits mannose-binding lectin. J Immunol. 2001 Mar 15;166(6):4148-53.
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C60	RIEBEN et al., Immunoglobulin M-enriched human intravenous immunoglobulin prevents complement activation in vitro and in vivo in a rat model of acute inflammation. Blood. 1999 Feb 1;93(3):942-51.
C61	ROOS et al., Human IgA activates the complement system via the mannan-binding lectin pathway. J Immunol. 2001 Sep 1;167(5):2861-8.
C62	ROOS et al., Therapeutic inhibition of the early phase of complement activation. Immunobiology. 2002 Sep;205(4-5):595-609. Review.
C63	ROOS et al., Functional characterization of the lectin pathway of complement in human serum. Mol Immunol. 2003 Jan;39(11):655-68.
C64	RUSSELL et al., Anti-inflammatory activity of human IgA antibodies and their Fab alpha fragments: inhibition of IgG-mediated complement activation. Eur J Immunol. 1989 Dec;19(12):2243-9.
C65	STAHL, The Immune System – Complementary Medicine. The Economist. 2000 May 13; 26-7.
C66	STAHL, New Inflammatory Pathway Discovered. Genetic Engineering News. 2000 May 15; 20(3):27-8.
C67	STAHL et al., Reperfusion injury in surgery. Role of the endothelium, oxidative stress and complement activation (Invited review). New Surgery. 2001; 1:62-6.
C68	STAHL et al., Role for the alternative complement pathway in ischemia/reperfusion injury. Am J Pathol. 2003 Feb;162(2):449-55.
C69	SZEBENI et al., Liposome-induced pulmonary hypertension: properties and mechanism of a complement-mediated pseudoallergic reaction. Am J Physiol Heart Circ Physiol. 2000 Sep;279(3):H1319-28.
C70	SZEBENI et al., Hemodynamic changes induced by liposomes and liposome-encapsulated hemoglobin in pigs: a model for pseudoallergic cardiopulmonary reactions to liposomes. Role of complement and inhibition by soluble CR1 and anti-C5a antibody. Circulation. 1999 May 4;99(17):2302-9.
C71	TAUB et al., A monoclonal antibody against the platelet fibrinogen receptor contains a sequence that mimics a receptor recognition domain in fibrinogen. J Biol Chem. 1989 Jan 5;264(1):259-65.
C72	TOFUKUJI et al., Anti-C5a monoclonal antibody reduces cardiopulmonary bypass and cardioplegia-induced coronary endothelial dysfunction. J Thorac Cardiovasc Surg. 1998 Dec;116(6):1060-8.
C73	WALLIS et al., Localization of the serine protease-binding sites in the collagen-like domain of mannose-binding protein: indirect effects of naturally occurring mutations on protease binding and activation. J Biol Chem. 2004 Apr 2;279(14):14065-73. Epub 2004 Jan 14.
C74	WALSH et al., Role of complement in myocardial ischemia and infarction. In: Szebeni J, editor. The Complement System. Novel Roles in Health and Disease. Kluwer Academic Publishers. Massachusetts, June 2004.
C75	WALSH et al., Myocardial Ischemia-reperfusion injury is dependent on lectin complement activation. American College of Cardiology. 2004 Mar 10; 11:15am-11:30am (Presentation Abstract).
C76	ZHAO et al., Anoxia and reoxygenation of human endothelial cells decrease ceramide glucosyltransferase expression and activates caspases. FASEB J. 2003 Apr;17(6):723-4. Epub 2003 Feb 05.
C77	ZHAO et al., Identification of human mannose binding lectin (MBL) recognition sites for novel inhibitory antibodies. Hybridoma and Hybridomics. 2002 Feb;21(1):25-36.
C78	ZHAO et al., Murine model of gastrointestinal ischemia associated with complement-dependent injury. J Appl Physiol. 2002 Jul;93(1):338-45.

EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.